Attny. Docket No. SMC-PT008

# IAP15 Rec'd PCT/PTO 08 MAR 2007

Express Mail No. EV748353828US

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL LETTER TO THE UNITED STATES			ATTORNEY'S DOCKET NUMBER SMC-PT008	
DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		
	ATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	10/574,320 PRIORITY DATE CLAIMED	
	PCT/IN04/00306 September 29, 2004 October 1, 2003  TITLE OF INVENTION A CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION AND A PROCESS FOR PREPARING			
	THE SAME	EASE PHARMACEUTICAL COMPOSI	TION AND A PROCESS FOR PREPARING	
Himadri	NT(S) FOR DO/EO/US i Sen et al.			
Applican	t herewith submits to the United Sta	ates Designated/Elected Office (DO/EC	O/US) the following items and other information:	
1.	This is a FIRST submission of items co	ncerning a submission under 35 U.S.C. 371		
2. 🗶	This is a <b>SECOND</b> or <b>SUBSEQUENT</b> s	submission of items concerning a submission	n under 35 U.S.C. 371.	
3.	This is an express request to begin nation (5), (6), (9) and (21) indicated below.	onal examination procedures (35 U.S.C. 37	1(f)). The submission must include items	
4.	The US has been elected (Article 31).			
5.	A copy of the International Application	n as filed (35 U.S.C. 371(c)(2))		
	a. is attached hereto (required	only if not communicated by the Internation	al Bureau).	
	b. has been communicated by	the International Bureau.		
	c. is not required, as the application was filed in the United States Receiving Office (RO/US).			
6. 📙	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).			
	a. is attached hereto.			
	b. has been previously submitted under 35 U.S.C. 154(d)(4).			
7. $\square$	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))			
	a. are attached hereto (required only if not communicated by the International Bureau).			
	b. have been communicated by the International Bureau.			
	c. have not been made; however, the time limit for making such amendments has NOT expired.			
	d. have not been made and w	vill not be made.		
8.	An English language translation of the	e amendments to the claims under PCT Arti	cle 19 (35 U.S.C. 371(c)(3)).	
9. 🗙	An oath or declaration of the inventor(	(s) (35 U.S.C. 371(c)(4)).		
10.	An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).	e annexes of the International Preliminary Ex	kamination Report under PCT	
Items 11 to 20 below concern document(s) or information included:				
11.	An Information Disclosure Statement	under 37 CFR 1.97 and 1.98.		
12.	An assignment document for recording	g. A separate cover sheet in compliance wit	h 37 CFR 3.28 and 3.31 is included.	
13. 🔲	A preliminary amendment.			
14.	An Application Data Sheet under 37 C	CFR 1.76.		
15.	A substitute specification.			
16.	A power of attorney and/or change of	address letter.		
17. 🔲	A computer-readable form of the sequ	ence listing in accordance with PCT Rule 13	3ter.2 and 37 CFR 1.821- 1.825.	
18.	A second copy of the published Interna	ational Application under 35 U.S.C. 154(d)(4	s).	
19. 🗆	A second copy of the English language	e translation of the international application	under 35 U.S.C. 154(d)(4).	

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

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20. Other items or information:  Power of Attorney to Customer Number 3824 appears in Declaration; Communication in Response to Notification of Missing Parts, Copy of Notification of Missing Requirements  The following fees have been submitted  The following fees have been submitted  11. Basic national fee (37 CFR 1.492(a)).  22. Examination fee (37 CFR 1.492(a)).  23. Examination fee (37 CFR 1.492(a)).  34. If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	10/574,320 INTERNATIONAL APPLICATION NO. (if known, see 37 CFR 1.5)  PCT/IN04/00306			SMC-PT008			
21.	Power of Att	orney to Custo	mer Number 36		tion; Communica	tion in Response to	Notification of
22.	The fol	lowing fees have b	een submitted			CALCULATIONS	PTO USE ONLY
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	21. 🔲 Bas	sic national fee (37	CFR 1.492(a))		\$300	\$	
by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	22.	mination fee (37 C	FR 1.492(c))				<u> </u>
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$ <sup>-</sup>		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) and 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) and 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) and 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.821(c)).  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof.  RATE  100	If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)				\$		
sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  Total Sheets  Extra Sheets  Number of each additional 50 or fraction thereof.  RATE  -100 =   /50 =   x\$250   \$  Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS  NUMBER FILED  NUMBER EXTRA  RATE  Total claims  -20 =   x\$50   \$  Independent claims  -3 =   x\$200   \$  MULTIPLE DEPENDENT CLAIM(S) (if applicable)   + \$360   \$  MULTIPLE DEPENDENT CLAIM(S) (if applicable)   + \$360   \$  TOTAL OF ABOVE CALCULATIONS =   \$130    Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL =   \$130    Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE =   \$130    Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		TOTAL OF 21, 22	2 and 23 =	,, ,		0	
thereof (round up to a whole number)  -100 =   750 =   x \$250   \$  Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS   NUMBER FILED   NUMBER EXTRA   RATE   \$  Total claims   -20 =   x \$50   \$  Independent claims   -3 =   x \$200   \$  MULTIPLE DEPENDENT CLAIM(S) (if applicable)   + \$360   \$  MULTIPLE DEPENDENT CLAIM(S) (if applicable)   + \$360   \$  MULTIPLE DEPENDENT CLAIM(S) (if applicable)   + \$360   \$  Forcessing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).   + \$  TOTAL NATIONAL FEE   \$130    Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   + \$  TOTAL FEES ENCLOSED   \$130   Amount to be refunded:   \$  Amount to be   \$	Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).				·		
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS NUMBER FILED NUMBER EXTRA RATE \$  Total claims -20 =	Total Sheets Extra Sheets Number of each additional 50 or fraction RATE						
after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS NUMBER FILED NUMBER EXTRA RATE  Total claims -20 =	- 100 =	/50 =			x \$250	\$	I
Total claims -20 =					oath or declaration	\$ 130	
Independent claims  - 3 =	CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$  TOTAL OF ABOVE CALCULATIONS = \$130  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$130  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$130  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + TOTAL FEES ENCLOSED = \$130  Amount to be refunded: \$  Amount to be refunded: \$	Total claims		- 20 =		x \$50	\$	
TOTAL OF ABOVE CALCULATIONS = \$ 130  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$ 130  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$ 130  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + TOTAL FEES ENCLOSED = \$ 130  Amount to be refunded: \$ Amount to be	Independent clai	ims	- 3 =		x \$200	\$	
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Amount to be refunded:  Amount to be \$ \$ Amount to be \$ \$					st be accompanied +	\$	
refunded: \$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\				TOTAL F	EES ENCLOSED =	\$ 130	
					·	refunded:	\$
							\$

PTC-1390 (Rev. 07-2005)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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а. 🔲	A check in the amount of \$ to cover	er the above fees is enclosed.		
ь. 🗆	Please charge my Deposit Account No in the ar A duplicate copy of this sheet is enclosed.	mount of \$ to cover the above fees.		
c. 🗶	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0493 . A duplicate copy of this sheet is enclosed.			
d. 🗵	Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.			
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.				
USPT Volpe United 30 So	LL CORRESPONDENCE TO: TO Customer Number 3624 and Koenig, P.C. d Plaza, Suite 1600 uth 17th Street delphia, PA 19103	SIGNATURE Robert J. Ballarini NAME 48,684 REGISTRATION NUMBER		

SMC-PT008

March 8, 2007

Our File:

Date:

#### **PATENT**

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the **PATENT APPLICATION** of:

Sen et al.

**Application No.:** 10/574,320

Confirmation No.: 5871

Filed: Not Yet Known

For: A CONTROLLED RELEASE

PHARMACEUTICAL COMPOSITION AND A PROCESS FOR PREPARING

THE SAME

Group:

Not Yet Known

Examiner:

Not Yet Known

COMMUNICATION IN RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office mailed from the Office on February 21, 2007, the following are enclosed:

Copy of the Notification of Missing Requirements Under 35
 U.S.C. 371;

Applicant: Sen et al. Application No.: 10/574,320

- 2. Fully executed Declaration and Power of Attorney to Customer No. 3624; and
- 3. Payment of the surcharge fee of \$130 (Form PTO-2038) for a large entity.

It is respectfully submitted that all formalities have been met.

Respectfully submitted,

Sen et al.

Robert J. Ballarini

Registration No. 48,684

(215) 568-6400

Volpe and Koenig, P.C. United Plaza, Suite 1600 30 South 17th Street Philadelphia, PA 19103

RJB/pp Enclosures (3)

1: 03/13/2007 JBALINAN 00000063 10574320 01 FC:1617 130.00 OP



### United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginis 22313-1450

	U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	AT	TY. DOCKET NO.
	10/574,320	Himadri SEN	S	SMCPT008
		RECEIVED	INTERNATIONAL APPLICATION NO.	
		AM/PM	PCT/IN04/00306	
624 OLPE AND KOENIG, P.C.		FEB 2 8 7307	I.A. FILING DATE	PRIORITY DATE
			09/29/2004	10/01/2003

3624 VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103

VOLPE & KOENIG, P.C.

CONFIRMATION NO. 5871 371 FORMALITIES LETTER

\*OC000000021287176\*

Date Mailed: 02/21/2007

# NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/31/2006
- Copy of the International Search Report filed on 03/31/2006
- Preliminary Amendments filed on 03/31/2006
- Information Disclosure Statements filed on 03/31/2006
- U.S. Basic National Fees filed on 03/31/2006
- Priority Documents filed on 03/31/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath
  or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the
  missing items identified in this letter.

### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

\$130 Surcharge.

DOCKETED FOR 4/21/07 Thissing Regunements

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FRANCINE YOUNG

Telephone: (703) 308-9140 EXT 215

#### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/574,320	PCT/IN04/00306	SMCPT008

FORM PCT/DO/EO/905 (371 Formalities Notice)